## **Summary of Opinions**

- Dr. King has provided no valid economic basis to conclude that off-label marketing of Neurontin indirectly influenced all, or substantially all, physicians prescribing Neurontin
- Dr. King's analysis does not prove that any specific Neurontin prescription was caused by any alleged misrepresentation by Defendants
- Dr. King admittedly has not done an analysis specific to Mr. Smith and the facts of this case
- Dr. King's opinions regarding the effect of off-label promotion of drugs generally and Neurontin specifically are flawed and unsupported

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## **Off-Label Prescribing**

- Off-label prescribing by physicians is common, accepted clinical practice
- Physicians often conclude that an off-label treatment is in best interests of patient
- Physicians need to treat patients for conditions where there is no FDA-approved drug or few treatment options
- New medical discoveries outpace FDA approval process

## **Factors Influencing Off-Label Prescribing**

- Patient-specific factors
  - Contraindications
  - Side effect profile
  - Response to other treatments
- Physician-specific factors
  - Positive experience with drug or similar drugs for off-label use
  - Physicians receive information about off-label use from many sources
- Neurontin-specific factors
  - Lack of drug-drug interactions and contraindications
  - Demonstrated efficacy for off-label uses
  - 2002 approval for treating PHN, a type of neuropathic pain Case 3:05-cv-00444 Document 175-2 Filed 04/27/10 Page 3 of 4 PageID #: 4047

## Flaws in Dr. King's Analysis

- Dr. King has not performed a valid causation analysis
  - Correlation vs. Causation
- Dr. King's reliance on general pharmaceutical literature is misplaced and doesn't support specific conclusions about Neurontin
- Claim that effects of off-label marketing of Neurontin would continue virtually unabated after promotion is terminated is unsupported
- Dr. King's claim about Defendants' marketing expenditures vs. costs of research and development is flawed

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